

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
93-R-0391

CUSTOMER NO.
1737

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

MEDIMMUNE VACCINES, INC.
297 NORTH BERNARDO AVENUE
MOUNTAIN VIEW, CA 94043

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3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experiments. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		38			38
7. Hamsters			113		113
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets	32	1353		67	1452
Cotton Rats			20		20

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)



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DATE SIGNED






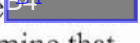
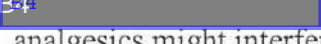

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Column E Explanation

1. Registration Number: **93-R-0391**
2. Number of animals used in these studies: **67**
3. Species (common name) of animals used in the study: **Ferrets**
4. Explain the procedure producing pain and/or distress.

The 67 ferrets assigned to Block E were used in two different study types: (a)  research studies and 

- (a)  research studies involve understanding the  or  of  when used in susceptible individuals. The ferret is the only laboratory animal model that exhibits clinical signs  similar to people   ferrets. Therefore, ferrets are the most relevant animal model to use for these studies. Ferrets are  with either   which may cause a mild to moderate . Animals are observed and those that develop significant clinical signs or infection such as  are placed in Block E since they will have experienced some unrelieved  and due to the study design which does not allow for alleviation of these signs with analgesics or  drugs. Animals are given supportive care such as food treats and fluids as needed.
- (b)  are mandated by the FDA (see 6. below). Ferrets are  with the    virus as a positive control. Some of the  animals will develop clinical signs of  such as  and . Only the animals which exhibit a significant  are classified as ill and therefore are assigned USDA category E. The test runs for three days from  to euthanasia of all animals and tissue collection for analysis.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
- (a) In  research studies, analgesics cannot be used because many analgesics also have  effects which include the  and  which would affect the very physiological functions that are under study – responses of the animal's  system to the   or the s. Methods used to determine that analgesics might interfere with test results are based upon scientific publications of adverse responses to analgesics in animals and humans and upon known mechanisms of actions of these analgesics.

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Literature search databases, dates and key words:

B4

- (b) The [B4] in the [B4] assay is used as a positive control against which are measured the [B4] and performance of the [B4]. The use of analgesics in these animals would invalidate this assessment.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: Food and Drug Administration (FDA) 21 CFR 610.1

"No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with the standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies."

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